

PRIA Fee Category Table – Inert Ingredients

Table 18.

| EPA No. | New CR No. | Action | Decision Review Time (Months) [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote1"] | FY'17 & FY'18 Registrati on Service Fee (\$) |
|--|------------|---|--|--|
| [HYPERLINK "http://www2.epa.gov/pria-fees/i001-pria-fee-category"] | 186 | Approval of new food use inert ingredient [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote3"] | 13 | 27,000 |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i002-pria-fee-category"] | 187 | Amend currently approved inert ingredient tolerance or exemption from tolerance; new data [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 11 | 7,500 |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i003-pria-fee-category"] | 188 | Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 9 | 3,308 |

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|--|------------|--|--|--|
| [HYPERLINK "http://www2.epa.gov/pria-fees/i004-pria-fee-category"] | 189 | Approval of new non-food use inert ingredient [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 6 | 11,025 |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i005-pria-fee-category"] | 190 | Amend currently approved non-food use inert ingredient with new use pattern; new data [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 6 | 5,513 |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i006-pria-fee-category"] | 191 | Amend currently approved non-food use inert ingredient with new use pattern; no new data [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 3 | 3,308 |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i007-pria-fee-category"] | 192 | Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert- | 4 | 1,654 |

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|--|------------|--|--|--|
| | | ingredients" \l "footnote2"] | | |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i008-pria-fee-category"] | 193 | Approval of new or amended polymer inert ingredient, food use [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 5 | 3,749 |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i009-pria-fee-category"] | 194 | Approval of new or amended polymer inert ingredient, non-food use [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 4 | 3,087 |
| [HYPERLINK "http://www2.epa.gov/pria-fees/i010-pria-fee-category"] | 195 | Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 6 | 1,654 |
| i011 | 196 (new) | Approval of new food use safener with tolerance or exemption from tolerance[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee- | 24 | 597,683 |

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|---------|------------|--|--|--|
| | | category-table-inert-ingredients" \l "footnote2"] ⁽⁵⁾ | | |
| I012 | 197 (new) | Approval of new non-food use safener[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] ⁽⁵⁾ | 21 | 415,241 |
| I013 | 198 (new) | Approval of additional food use for previously approved safener with tolerance or exemption from tolerance[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 15 | 62,975 |
| I014 | 199 (new) | Approval of additional non-food use for previously approved safener[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 15 | 25,168 |
| I015 | 200 (new) | Approval of new generic data for previously approved food use safener[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert- | 24 | 269,728 |

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|---------|------------|---|--|---|
| | | ingredients" \l "footnote2"] | | |
| 1016 | 201 (new) | Approval of amendment(s) to tolerance and label for previously approved safener[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients" \l "footnote2"] | 13 | 55,776 |

¹A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

²If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time line for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

³If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

⁴Any other covered application that is associated with and dependent on the HSRB review will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.

⁵Any other covered application that is associated with and dependent on the SAP review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.

⁶An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

⁷Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

⁸If a new safener is submitted in the same package as a new active ingredient, and that new active ingredient is determined to be reduced risk, then the safener would get the same reduced timeframe as the new active ingredient.